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EXAMINER
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1648	

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9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/026,314	Applicant(s) KAYLOR ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *4,5,7-10,20-24,26,28-31 and 35-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,11-20,25,27 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, and the species wherein the first and second analytes are from a bacterium and a virus, in Paper Nos. 6 and 8 is acknowledged. The traversal is on the ground(s) that the limitation to a single species defeats the purpose of the invention, which is to differentiate between multiple diseases or disorders. This is not found persuasive because each of the described inventions is used to differentiate between a different set of possible diseases or disorders. As such, absent a determination that the linking concept of the test device with multiple sites is allowable, each of the separate species requires a separate search not coextensive with the searches required for the other methods.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 4, 5, 7-10, 20-24, 26 28-31, and 35-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on March 7, 2002 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Drawings

4. The drawings are objected to because the different views of the invention that are portrayed in the figures are incorrectly identified according to 37CFR 1.84 (u)(1), which requires that each of the different views be "identified by the same number followed by a capital letter." In this case, this requires that (for example), instead of referring to Figure 1 and Figure 1A, the specification should identify and refer to these views as Figures 1A and 1B, respectively.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claims 1, 3, 17, and 20 are objected to because of the following informalities: each of these claims includes a list of claim embodiments (e.g. the listing of groups (i)-(v) in claims 1 and 17, and the listing of groups (ii)-(v) in claims 3 and 20). However, while the applicant has separated most of the members of these groups with commas, no commas are provided separating the last group members from the penultimate members. Appropriate correction is required.

6. Claim 2 is objected to because of the following informalities: the claim reads "wherein the second analyte that is selected from a different group from the first analyte." The "that" should be removed from the claim. Appropriate correction is required.

7. Claim 20 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. This claim describes an embodiment of the claimed method wherein "the first analyte is selected from group (i) and the second analyte is selected from group (ii), group (iii), group (iv) or group (v). However, claim 20 also depends (indirectly) from claim 18. This claim requires that the second analyte of the device used in the method be a member of one of groups (i)-(iv). Because claim 18 states that the second analyte is selected from a different set of analytes than are identified in claim 20, and because claim 20 includes possible substituents not included in claim18, claim 20 is not properly dependant on claim 18.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-3, 6, 11-20, 25, 27 and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. These claims each read on methods of determining the

cause of a malady in an animal by testing a sample for analyte binding in a biosensor device. However, the claims do not indicate how the analyte detection relates to the stated purpose of determining the cause of the malady.

For the purposes of the other rejections in this action, unless otherwise stated, these claims will be treated as though such a step was part of the claimed method.

10. Claims 11, 17-20, 25, 27, and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. These claims read on methods of determining the cause of a malady by detecting an analyte in a sample, wherein said detection comprises evaluating a plurality of test sites in a described device for a change indicating the binding of an analyte. In the identified claims, this detection includes a step of "observing light that has been reflected from or transmitted through [a] test site for diffraction..." However, the claims do not indicate the what the relationship of the light diffraction has to the indication that analyte binding has occurred. It is suggested that the Applicant amend the claims to include a step similar to "determining that binding has occurred where diffraction of said light is observed."

For the purposes of other rejections in this action, unless stated otherwise, the claims will be read as though they include such a step.

11. Claims 20 and 27are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 depends (indirectly) from claim 18, which requires that the

second analyte of the device used in the method be a member of one of groups (i)-(iv). However, claim 20 requires that the second analyte be from one of groups (ii)-(v). Thus, the limitations of claim 20 are inconsistent with those of claim 18. Because of this inconsistency, it is unclear what groups the second analyte of claim 20 may be chosen from. The claim is therefore indefinite.

Claim 27 depends from clam 20.

For the purposes of other rejections in this action, unless stated otherwise, these claims will be treated as though they were properly dependent on (i.e. not in conflict with) claim 18.

12. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim describes the claimed method, wherein either the first or second binder is sialic acid or an antibody to influenza. It is not clear what the claim is referring to by the term influenza. The specification describes both the Influenza virus, and the bacteria Haemophilus influenza as potential analytes detectable by the method. Pages 2 and 9, respectively. Thus, it is unclear to which pathogenic species the claim is being directed.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-3, 6, 12, 13, 14, and 15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Charych et al., U.S. Patent 6,022,748. These claims read on methods of determining the cause of a malady in an animal by detecting pathogens or allergens in a sample from the animal. The claims are further limited to embodiments wherein the first analyte is a bacterial analyte, and the second analyte is a viral analyte.

Charych teaches a device (composition) useful for the detection of analytes in a sample, and to methods of using it. See e.g., abstract, col. 5, lines 16-45, and claim 1. Although the reference teaches embodiments that include binding agents for individual analytes, it also teaches the incorporation of binding agents for multiple agents. Col. 15, lines 11-41; col.19, lines 6-48; and col. 22, lines. The reference teaches that such arrays are useful for the identification of a single analyte in a sample comprising several compounds, or for the detection of multiple analytes. Col. 19, supra. The analytes are detected by observing for changes in the color of test sites, such changes indicating that analyte binding has occurred. Abstract. Among the analytes that the device and methods can be used to detect in a sample are both virus and bacteria. Col. 22, lines 48-51. Thus, the patent teaches a device that can be used in the presently claims method of determining the cause of a malady in an animal.

As indicated above, Charych also teaches methods of using the claimed device. Among the uses for which the described device may be used is as a diagnostic device. Col. 5, lines 30-45. Thus, the reference teaches a device with the capacity to detect a pathogen (including viruses and bacteria) in a sample, that such a device may be able to detect a plurality of potential pathogens, and that the device is useful for diagnostic purposes.

Because the reference teaches that the device is useful as a diagnostic device, one skilled in the art would have understood that the device was useful for the determination of a source of a malady. See e.g., definition for diagnosis in the On-line Medical Dictionary (stating that the term is understood to mean the determination of the nature of a disease, which would include the identification of its cause). The combination with the commonly understood meaning of "diagnosis, and the teachings that the device can detect pathogens, provides an implicit teaching that the device is usable for the detection of the source of maladies.

It is also noted that the reference does not specifically state that the device consists of a "plurality of integrates, discrete sites," such would have been understood from the use of the descriptor "array" in the specification. Col. 13, lines 25-30, and col. 19, lines 25-44. Thus, the reference anticipates the claimed methods for the determination of a source of a malady in an animal.

16. Claims 1-3, 6, 11-15, 17-20, 25, 27 32, and 33 are r rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,399,295 (the 295 patent) in view of Charych et al. as described above. The present application claims a method of determining the cause of a malady by detecting analytes in a sample.

The 295 patent teaches a method of detecting analytes in a sample through a method using light diffraction to detect analytes, and a wicking agent. Abstract, columns 5-8. While the present claims do not require a wicking agent, they do not exclude such an agent from the device. However, the patent teaches a general analyte detection device and method. The present claims require that the method be a method for the determination of a cause of a malady.

Charych has been described above. It teaches a method for the detection of analytes, and that such a method may be used for diagnostic purposes. One of ordinary skill in the art would have recognized that the method disclosed by the 295 patent could be applied as a diagnostic test in a manner akin to the Charych device. Further, it would also have been obvious to modify the device of the 295 patent such that it would be capable of detecting multiple analytes as suggested in the Charych patent. Thus, the combination of these references renders obvious the presently claimed method of determining the cause of a malady.

The 295 patent has a common inventor, and assignee, with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in

the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

17. Claims 1 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charych as applied to claims 1-3, 6, 12, 13, 14, and 15 above, and further in view of either Minshull et al., U.S. application Publication 2002/0127623, or Batt et al., Proceedings of the ERDEC Scientific Conference on Chemical and Biological Defense Research, Aberdeen Proving Ground, MD, United States, Nov. 17-20, 1998 (1999), Meeting Date 1998, 233-243, Dorothy A. (Ed.), National Technical Information Service, Springfield, Va. Claim 1 has been described above. Claim 16 describes the method of claim 1 wherein the test device is a handheld device.

Charych has been described in part above. This reference also indicates that the method disclosed therein achieves certain benefits over the biosensors of the prior art, i.e. they maintain the benefits of the prior art, but do not require energy sources so that they may be useful for "routine field work and home use." Col. 1, lines 55-63. Thus, the patent indicates that the disclosed device is easily portable. However, the reference does not indicate that the device is hand held.

Minshull also teaches a biosensor device. Abstract. The reference teaches that the device disclosed therein, which requires more electronics than Charych, can be installed into a hand-

held biosensor device "suitable for home or point of care, e.g. for clinic or hospital use." Pages 7-8, paragraphs 0073-0075. Such a device is also described by Batt. See, abstract, and pages 238-241. Batt also teaches that the device may be constructed such that multiple analyte binding substances are attached to the same substrate. Page 238. The method of analyte detection used in each of these references is similar to that used in Charych. Given the similarity of the uses, and the simplicity of the Charych detector, it would have been obvious to those in the art to combine these references so as to make a hand-held device incorporating the detection device described by Charych. In view of the suggestions by Charych regarding the portability and robustness of the device disclosed therein, one of ordinary skill in the art would have had a reasonable expectation of success in performing such a combination.

18. Claims 1-3, 6, 11-15, 17-20, 27, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Everhart et al., U.S. Patent 6,060,256 (of record in the IDS of March 7, 2002). These claims read on methods of determining the cause of a malady using a device as described above, wherein the evaluation of the test sites for an indication that binding has occurred comprises an observing light reflected from, or transmitted through, the test sites for diffraction. The claims have been described in part above. This rejection is focusing on embodiments of the claimed method as described above, wherein the detection of bound analytes comprises evaluating the test sites in the described device for a change indicating the binding of an analyte. This detection step includes a step of observing light that has been reflected from or transmitted through the test site for diffraction, whereby an observed diffraction indicates that an analyte has been bound, and that such analyte is a potential cause of the malady.

This Everhart reference teaches the making and operation of devices that can include one or more test sites comprising ligands for analytes of interest. Columns 1-3. Among the potential analytes identified by the reference are viruses and bacteria. Col. 3, lines 59-62, and col. 5, lines 27-45. The reference also the device can detect analytes that indicate the presence of an infectious disease. Col. 6, lines 49-50. Furthermore, the reference also teaches that the device may be constructed such that a single support comprises test sites for multiple analytes. Col. 8, lines 25-37. The reference therefore teaches as device that may be used in the presently claims.

Everhart also teaches the described device has utility in health diagnostic applications. Col. 3, lines 7-15. Thus, the patent suggests the use of the described device to help in the diagnosis of a disease. Because the reference also teaches that the device can detect antigens that indicate the presence of an infectious disease, it would have been obvious to those in the art to have used the device in a method of determining the cause of malady. Thus, the patent renders the methods of the identified claims obvious.

19. Claims 1-3, 6, 11-15, 17-20, 25, 27 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Everhart (U.S. Patent 6,060,256) as applied to claims 1-3, 6, 11-15, 17-20, 27, 32, and 33 above, and Charych as applied to claims 1-3, 6, 12, 13, 14, and 15 above. The claims have been described in part above. This rejection is focusing on embodiments of the claimed method as described above, wherein one of the first or second binders is sialic acid, or an antibody to influenza. For the purposes of this rejection, it is being assumed that the "influenza" referred to is the influenza virus. The teachings of Everhart have

been described above. This patent does not specifically identify the influenza virus as a potential analyte, although it does refer to viruses generally.

The teachings of Charych have also been described in part above. This reference further teaches that among the potential binding agents that may be used in the device to bind analytes is sialic acid, which can bind to the influenza virus, and other pathogenic organisms. Col 20, lines 58-65. However, the reference does not teach a method of detecting analyte binding through observing light diffraction.

In view of the fact that both references are describing similar methods of detecting analytes in samples, and that both methods use similar materials, and can be used for similar purposes, it would have been obvious to those in the art to combine the teachings of these two references. It would therefore also have been obvious to use the binding agents of Charych in the device of Everhart, or to modify the device of Charych as suggested by Everhart. Because Charych teaches the use of sialic acid to bind the influenza virus an analyte, and because Everhart teaches a method of analyte detection involving the observation of light diffraction, the method of claim 25 is rendered obvious by these two references. Because both references teach similar devices, the only difference being the methods of detecting the bound analyte, one of ordinary skill in the art would have had a reasonable expectation of success in such a combination.

20. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Everhart in view of Charych as applied to claims 1-3, 6, 11-15, 17-20, 25, 27 32, and 33 above, and further in view of either Minshull, or Batt, as applied to claim 16 above. Claim 34 describes the method of

claim 17 (using the diffraction mode of analyte detection), wherein the device is a handheld device. In addition to the other teachings described above, Everhart also teaches that the biosensor device described therein requires no electronics other than a light source. Col. 3, lines 65-67. Thus, one skilled in the art, when reading this reference in view of the teachings of Charych and of Minshull or Batt as described above, would have found it equally obvious to combine the teachings of these references and make the Everhart device hand-held. They would have a reasonable expectation of success in doing so for the same reasons as indicated above with the Charych device.

Double Patenting

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 1-3, 6, 11-15, 17-20, 25, 27 32, and 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3,14-16, 26-28, and 35-37 of U.S. Patent No. 6,399,295 (the 295 patent) in view of Charych et al. as described above. The 295 patent teaches a method of detecting analytes in a sample through a

method using light diffraction to detect analytes, and a wicking agent. Charych has been described above. It does not teach the use of a wicking agent or analyte detection through diffraction, but does teach other aspects of the claimed method. The present application claims a method of determining the cause of a malady by detecting analytes in a sample using a method akin to that in the 295 patent. However, the present claims do not require a wicking agent. Such an agent is however disclosed in those parts of the specification describing the device used in the present claims. See, page 16, lines 5-34. Thus, the current claims are an obvious variation from the method claimed in t the 295 patent.

23. Claims 1-3, 6, 11, 12-15, 17-20, 27, and 32-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 17, 18, 20, 21, 32, and 37 of U.S. Patent No. 6,436,651. Although the conflicting claims are not identical, they are not patentably distinct from each other because, although the methods claims in the patent are not directed to methods of determining the cause of a malady, they are directed to methods for the detection of analytes in samples using a device similar to that of the present claims. Further, the patent also teaches that the device used in the method of the patent has utility a diagnostic tool (col. 3, lines 8-19) it would have been obvious to those in the art to use the method claimed in the patent as a method of determining the cause of a disease.

24. Claims 1-3, 6, 11-15, 17-20, 25, 27 32, and 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 14, 15, 23-25, 32, 33, and 41 of U.S. Patent No. 6,221,579 (of record in the IDS filed March 7, 2002); and

over that patent in view of Charych as described above. The '579 patent has teachings nearly identical to those of the Everhart '256 patent described above. See e.g., the teachings of columns 3-4; col. 6, lines 40 to col. 7, line 10; col. 8, lines 18-24, and 42-54. Those elements of the rejected claims that are not taught by the '579 patent have been described in the Charych patent as indicated above. It would have been obvious to combine these references for the same reasons as indicated with reference to Charych and the Everhart '256 patent above. Thus, the presently claims methods are obvious variations on the claimed methods of U.S. patent 6,221,579.

25. The above rejection is, in part, based on the specification of a previously issued patent, rather than the claims. In support of the use of this material, the examiner notes the following excerpt from MPEP section 804:

> When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.
>
> The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is

based. This is true even where elements are drawn from the specification describing the claimed invention, which are not elements in the claim itself.

Conclusion

26. No claims are allowed.

27. The following prior art references are made of record and are considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

St. John et al., Analytical Chemistry, Volume 70 (6), Pages 1108-1111 (March 1998). This reference teaches a method of detecting analytes on a printed optical grating through measuring the diffraction of light passed through the grating. The reference is therefore considered to be redundant to some of the teachings included in the Everhart references, and to render the use of light diffraction as a analyte detection device obvious.

WO 01/81921, naming Kaylor et al. as inventors; and EP 0276968, naming Gustafson et al. as inventors. These references are considered to be redundant to the Everhart (U.S. Patent 6,060,256) reference and the 295 patent.

U.S. Application Publication 2003/0104390, naming Etienne et al. as inventors. This reference teaches a device for the detection of pathogens causing a plant disease comprising a substrate surface with separate regions that can detect one or more plant pathogens. Pages 3. The reference is considered relevant in that it teaches methods of determining the causes of plant diseases that are similar to the presently claimed methods of doing so with animal diseases. The reference is not applied as art against the present claims because the reference teaches methods of detecting causes of plant, not animal, diseases, and because its teachings are redundant to those of several of the above references.

Morhard et al., Sensors and Actuators B 70:232-42. This reference teaches the use of diffraction-based detectors of pathogens useful for the early diagnosis and treatment of patients. This reference is not being applied above as redundant to the teachings of Minshull and Batt.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
July 10, 2003

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